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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

**SUBJECT: Comments on Docket 03D-0060, "Guidance for Industry Part 11, Electronic Records; Electronic Signatures – Scope and Application"**

I have two comments on this referenced draft. I am a senior consultant, not employed in industry, with seven years pharmaceutical industry experience on top of a full career having depth and breadth in engineering, software development and commissioning of computer based control systems. Applications cover a broad range from aircraft guidance systems, to pipeline SCADA systems to ultrasound imaging equipment and most recently qualifying pharmaceutical process and environmental control systems. Additionally, I have served as an expert on numerous related legal cases, hold patents, hold BSEE and MSEE degrees, and am licensed in electrical engineering.

First comment – on risk assessments

I strongly support the use of documented risk assessments as stated in paragraphs C (1) and (2). Further, I recommend that in any revision of Part 11 the FDA require written assessments and rationales for compliance of complex computer related systems paragraph 10.10(a) and for other paragraphs as appropriate.

Performing the risk assessment should increase the focus on what is important and in turn lead to reduced risk to the public and industry as well as reduced cost of compliance. Additionally, this should make adoption of newer technologies less costly and cumbersome leading to greater productivity.

It is critical however, that the risk assessments be performed by those having appropriate technical background for the technologies involved perhaps using cross-functional teams. Also the FDA should adequately review these assessments and perhaps issue a guideline for their use. The proper background for part 11 and computer related compliance includes Computer Science or related formal education.

03D-0060 C 25

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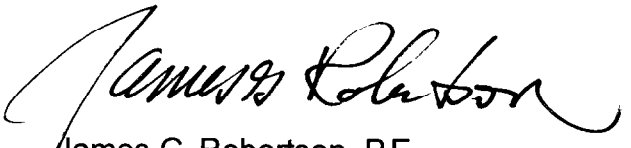
Second comment – on change control

In my experience, change control is the most difficult compliance issue for the pharmaceutical industry. It is imperative to think through the consequence of any change to software before it is implemented. Failure to do so can result in unanticipated and unknown changes to critical part 11 compliance features as well to other GMP critical functions. These changes can go unnoticed with possible troubling or tragic consequences.

I make no attempt to analyze why change control is a problem, but if it were easier to do and was less disruptive to normal production operations I suspect it would be more favorably viewed. A number of commercial systems are available to manage change control, software versioning and archiving. I suggest that the guideline include a recommendation to use such a system to minimize the likelihood that software is changed without authorization and approval.

Sincerely,



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